SSM HEALTH · CARE℠

February 26, 2009

Frank Torti, MD, MPH, Acting Commissioner
Food and Drug Administration
Center for Devices and Radiological Health (HFZ-500)
1350 Piccard Dr.
Rockville, MD 20852

Re: Unique Device Identification System; Request for Comments [Docket No. FDA-2008-N-0661]

Dear Doctor Torti:

On behalf of SSM Health Care, I am writing to express our commitment to improving the quality of care for the patients we serve.

SSM Health Care operates hospitals and other health care facilities in four states (Wisconsin, Illinois, Missouri and Oklahoma). Quality care for our patients is, has been and will continue to be our top priority. A "Unique Device Identification System" would be an important link in enhancing patient safety. SSM Health Care fully supports the Food and Drug Administration's (FDA) efforts to create a national unique device identification (UDI) system for medical devices.

Currently, it is easier for a consumer to learn that a microwave oven has been subject to a recall than it is for a health care facility to determine that a piece of medical equipment has been subject to a recall. While some notification currently exists, it is not conducted with consistency and application to all medical devices.

We appreciate the opportunity to comment on the FDA's January 15, 2009, Request for Comments published in the *Federal Register*. SSM Health Care strongly urges the FDA to move the rulemaking process forward immediately to implement a regulated, mandatory UDI system that is globally harmonized.

Unique device identification is the missing link to protect the safety of patients by improving processes for device recalls and corrections. The rapidly rising number of device recalls points to the need for UDI for effective management of recalls. More than 700 medical device recalls were issued in 2008, including more than 100 Class 1 recalls (defined as dangerous or defective products that predictably could cause serious health problems or death). Manufacturers also issue many "device corrections" that can have serious consequences for patients if not handled correctly. Because of the absence of UDI, SSM hospitals in our four states often must use a manual process to identify any recalled products.

477 N. Lindbergh Blvd.
St. Louis, MO 63141-7832
www.ssmhc.com
(314) 994 7800 *phone*
(314) 994 7900 *fax*

Malcolm Baldrige National Quality Award 2002 Award Recipient

UDI is essential to maximizing the value of electronic health records (EHRs). EHRs will require that data standards, including those for medical devices, are in place and used by all institutions to transfer information. A common vocabulary for medical devices is necessary for healthcare providers to be able effectively to document devices in patient records. In addition, the recently enacted American Recovery & Reinvestment Act contains $19 billion to encourage health information technology adoption through direct grants to providers as well as Medicare and Medicaid payment incentives. This substantial federal investment in HIT also speaks to the need for a UDI system as soon as possible.

Indeed, SSM Health Care, itself, is in the midst of rolling out the EPIC® electronic health records system in all of our facilities. Five of our facilities are already operating this system; two more are scheduled to begin using the system this year; and all of our facilities are on schedule to use the EPIC® system. This is a ten year, $329 million process that would be greatly enhanced by the availability of a UDI system.

The FDA has been working on this issue for more than five years. In that time, the agency has held several public stakeholder meetings, solicited comments and commissioned several studies. While SSM Health Care appreciates the open and transparent process the agency has followed, the time to act is now. UDI is too important to patient safety to delay any longer.

Specifically, in response to the questions posed by the FDA in its January 15, 2009 Request for Comments, SSM Health Care offers the following responses on how a national UDI system should be structured.

1. Which types of devices or particular devices should be subject to the requirements of a UDI system? Which types of devices or particular devices should be excepted?

We believe the UDI should be considered for all devices to improve recall processes, adverse event reporting and patient safety. The information that is included on the products should vary based upon the class of device. Therefore, it is recommended that FDA require basic information for all devices, and more extensive information in a data repository for those devices that require it.

2. What are the characteristics or aspects necessary to uniquely identify a device?

a. What characteristics are needed to uniquely identify a device?

The attributes or elements needed to create a UDI will vary based upon the classification of the device. Therefore it is important that the UDI system include a classification system that places the device into a class that will in turn determine the appropriate attributes. The UDI, at a minimum, should include manufacturer, product name, make, model, lot number, unique description, expiration date and unit of measure.

d. Should the UDI include a component that represents package size or packaging level?

UDIs should be implemented at the package level that is issued to the patient. This would ensure the identification of the device as it is provided (right product and right patient) and minimize the errors associated with the provider re-labeling the device for issue to the patient. The information included at the point of issue to the patient should be sufficient to identify the device and allow it to be linked to the provider database synchronized to the product data repository.

3. What should be the UDI's components?

a. Could existing standards, such as the standards used by GS1, Health Industry Business Communications Council (HIBCC), or others be used as a model for the UDI system? What are the advantages and disadvantages of these existing organizations and standards?

There is a clear advantage for using the GS1 system in that it has been in use by other industries for many years, it is recognized globally and it is committed to modifying its standards as needed for healthcare products. It has over 105 world-wide offices that allow it to have the global reach for healthcare products and it is currently used by other industries from which my hospital already buys products.

e. How should the UDI be created to ensure that UDIs are unique?

Identification systems for products are already prevalent in the grocery, food service, automotive and electrical industries. All of these industries have successfully adopted the GS1 system of identification and classification. We should not reinvent the wheel. Since my hospital purchases products from each of these industries, it makes sense to build upon what is already in place and utilize the GS1 system for medical devices.

5. ***How should the UDI be presented?***

a. Should we require human-readable UDIs or automatic identification of UDIs or both?

SSM Health Care supports the UDI being both human readable and encoded in automatic technology. The human readable information on the device should be limited to what is minimally required to properly identify the product before issuing to a patient.

<u>Questions for hospitals, nursing homes, and clinics</u>

3a. Using a UDI. If UDIs were placed on at least some medical devices, what functions could a UDI serve in your institution?

UDIs would immediately serve to quickly identify equipment subject to a recall. While there would be time spent in developing inventories containing the UDIs, this time would be less (and more productive) than the current system of locating equipment without a UDI when a recall is announced. Further, as we implement the EPIC® electronic health record systems in our

hospitals in four states, we would expect that this could become part of our electronic records so that, when recalls are announced, the identification process would be significantly reduced.

b. Expenses. What expenses do you foresee in attempting to capture and use UDIs placed on medical devices? If you foresee using UDIs, how would you modify operations in your facility?

It is, of course, difficult to predict expenses at this point. However, SSM would anticipate that, over time, our expenses would be less than our current expenses in identifying equipment subject to recalls. There would be an up front expense involved in the time and effort to enter new equipment UDI information into our systems. However, that would be more than made up in time saved when a recall is announced and equipment must be identified.

c. Adverse event reporting and recalls. How would capturing the UDI change your recall management or adverse event reporting? For recalls or adverse events involving the most serious device malfunctions or failures, how have problems in device identification impaired your recall management or adverse event reporting? Please describe the magnitude of the problems you have encountered.

While this information must, at this time, be anecdotal, we would observe that having a UDI will help in quickly identifying the specific unit which in turn would assist in identifying other units in the same production run that may be affected by the same malfunction. This will both help to identify equipment that must be taken out of service to avoid compromising patient safety help to save the expense of taking equipment out of service that might be affected by the malfunction but due to a lack of a UDI cannot be clearly excluded from the recall.

In closing, SSM Health Care thanks you for the opportunity to provide comments on a UDI and reiterate our strong support for a regulated, mandatory UDI that is globally harmonized. We look forward to working with you on this important issue that will ultimately improve patient safety, reduce medical errors, facilitate device recalls and improve device adverse event reporting.

Sincerely,

Stephen B. Hoven
Corporate Vice President - Public Affairs
314/994-7896
steve_hoven@ssmhc.com